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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,667	01/22/2002	Lance A Liotta	4239-60680	5252

36218 7590 10/06/2004
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EXAMINER

MINNIFIELD, NITA M

ART UNIT PAPER NUMBER

1645

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/913,667	Applicant(s) LIOTTA ET AL.	
	Examiner N. M. Minnifield	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28,34-39,44-51 and 53-87 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28,34-39,44-51 and 53-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) <u>2 sheets</u> | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>3082004</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7-19-04 1 sheet.</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicants' amendment filed July 19, 2004 is acknowledged and has been entered. Claims 29-33, 40-43 and 52 have been canceled. Claims 1-4, 6-9, 11, 16, 17, 19, 25, 26, 76 and 81 have been amended. New claims 84-87 have been added. Claims 1-28, 34-39, 44-51 and 53-87 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment to the claims and/or comments with the exception of those discussed below.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 1-28, 34-39, 44-51 and 53-83 (and now 84-87) are rejected under 35 U.S.C. 102(e) as being anticipated by Bonner et al (6251516).

The applied reference has a common inventor (Liotta and Emmert-Buck) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Bonner et al discloses a method of microdissection and analyzing proteins of interest (abstract). Bonner et al discloses methods and devices for the microdissection and molecular analysis of cellular samples, which may be used in

combination with a number of different technologies that allow for analysis of proteins from substantially pure populations or subpopulations of particular cell types (col. 1, l. 20-26; col. 2, l. 62-64; col. 4, l. 15-26; col. 6, l. 23-32; col. 8, l. 39-42; col. 8; col. 19). Bonner et al discloses improved methods to specifically examine genetic alterations in pre-invasive lesions of common epithelial tumors such as breast and prostate carcinoma (col. 2, l. 35-40). Bonner et al discloses that the proteins or cells of interest can be analyzed, visualized or identified by a variety of labels, histochemical stains, antibodies, etc (col. 4, l. 31-38). Bonner et al discloses that one or more cells of interest can be isolated via laser capture microdissection; abnormal cells or control cells (i.e. normal) can be obtained (cols. 10-11). Example 1 discloses collection and analysis of normal and tumor tissue (see cols. 20-21 and Table 1). Example 4 discloses analysis of normal and human prostate cancer (col. 23) and Example 5 discloses analysis of breast carcinomas (col. 25). The prior art anticipates the claimed invention. Since the Patent Office does not have the facilities for examining and comparing applicants' methods with the methods of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed methods and the methods of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

4. Applicant's arguments filed July 19, 2004 have been fully considered but they are not persuasive. The Liotta and Emmert-Buck Declarations under 37 CFR 1.132 filed July 19, 2004 are insufficient to overcome the rejection of claims 1-28, 34-39, 44-51 and 53-83 based upon Bonner et al 6251516 as set forth in the last Office action. The declarations are insufficient because they do not include

the correct citation of the US Patent. The claims were rejected based upon the disclosure of Bonner et al 6251516, not 6252516.

5. No claims are allowed.
6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

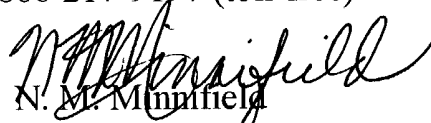
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 571-272-0864. The

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fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


N. M. Minnifield
Primary Examiner
Art Unit 1645

NMM
October 4, 2004